Resolutions

DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY | Resoluciones DINAVISA

National Directorate of Health Surveillance.

Resoluciones Año 2025

1. **DINAVISA RESOLUTION No. 330** WHICH PROVIDES FOR THE CREATION OF A SCIENTIFIC-TECHNICAL COMMITTEE (CCT) AS A CONSULTATION BODY ON MATTERS RELATED TO THE JURISDICTION OF THE NATIONAL HEALTH SURVEILLANCE DIRECTORATE.

2. **DINAVISA RESOLUTION No. 328** DATED SEPTEMBER 3, 2025: "BY WHICH THE REQUIREMENTS ARE ESTABLISHED FOR OBTAINING, RENEWING, UPDATING, TRANSFERRING, SUSPENSION AND CANCELING THE SANITARY REGISTRATION OF FOOD PRODUCTS, BEVERAGES AND FOOD ADDITIVES, INTENDED FOR HUMAN CONSUMPTION, BEFORE THE NATIONAL DIRECTORATE OF SANITARY SURVEILLANCE".
3. **DINAVISA RESOLUTION No. 327** DATED SEPTEMBER 2, 2025: "BY WHICH THE REQUIREMENTS FOR THE ISSUANCE OF THE COMPLEMENTARY ACCREDITATION CERTIFICATE OF THE HEALTH RESEARCH ETHICS COMMITTEES (CEIS) ARE ESTABLISHED."
4. **DINAVISA RESOLUTION No. 326** DATED SEPTEMBER 1, 2025: "BY WHICH THE CONDITIONS AND REQUIREMENTS ARE ESTABLISHED FOR OBTAINING, RENEWING AND UPDATING THE REGISTRATION OF THE ESTABLISHMENT OF FOOD, BEVERAGES AND FOOD ADDITIVES INTENDED FOR HUMAN CONSUMPTION, BEFORE THE NATIONAL DIRECTORATE OF HEALTH SURVEILLANCE.
5. **DINAVISA RESOLUTION No. 311** "WHICH ESTABLISHES THE TECHNICAL REQUIREMENTS FOR CONDUCTING STABILITY STUDIES OF SYNTHETIC ACTIVE PHARMACEUTICAL INGREDIENTS (IFAs), IN ACCORDANCE WITH THE GUIDELINES OF THE INTERNATIONAL COUNCIL FOR HARMONIZATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICAL PRODUCTS FOR HUMAN USE (ICH)"
6. **DINAVISA RESOLUTION No. 305** UPDATING THE REGULATIONS OF GOOD PRACTICES FOR MEDICINE QUALITY CONTROL LABORATORIES
7. **DINAVISA RESOLUTION No. 274** "WHICH APPROVES THE INTEGRAL PLAN FOR FOOD INSPECTION, SURVEILLANCE AND CONTROL AND THE FOOD CONTROL MATRIX WITHIN THE FRAMEWORK OF THE COMPETENCES OF THE NATIONAL HEALTH SURVEILLANCE DIRECTORATE.
8. **DINAVISA RESOLUTION No. 270** WHICH PROHIBITS THE MANUFACTURE, IMPORT, EXPORT, DISTRIBUTION, MARKETING AND USE OF RAW MATERIALS AND ORAL AND PARENTERAL MEDICINES CONTAINING THE ACTIVE INGREDIENT RANITIDINE THROUGHOUT THE TERRITORY OF THE REPUBLIC, AND PROVIDES FOR THE FINAL RENEWAL OF CURRENT HEALTH REGISTRATIONS, THE WITHDRAWAL FROM THE MARKET AND THE FINAL DISPOSITION OF PRODUCTS IN EXISTENCE.

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9. **DINAVISA RESOLUTION No. 265** ESTABLISHING SANITARY REQUIREMENTS AND CONDITIONS FOR ESTABLISHMENTS DEDICATED TO THE MARKETING OR DISTRIBUTION OF MEAT PRODUCTS OF POULTRY ORIGIN AND THEIR CUTS, IN ACCORDANCE WITH THE COMPETENCES OF DINAVISA.
10. " **DINAVISA RESOLUTION No. 261** REGULATING THE SIMPLIFIED PROCESS FOR ISSUING AND RENEWING THE SANITARY REGISTRATION CERTIFICATE FOR FOOD PRODUCTS (RSPA) UNDER THE AUTOMATIC SANITARY NOTIFICATION MODALITY IN COMPLIANCE WITH THE ANMAT-DINAVISA AGREEMENT"
11. **DINAVISA RESOLUTION No. 228** DATED JUNE 20, 2025: "BY WHICH THE GOOD REGULATORY PRACTICES FOR DINAVISA ARE APPROVED IN ACCORDANCE WITH THE GUIDE (BPR) IN THE ATTACHED ANNEX AND DINAVISA RESOLUTION 320/2023 IS REPEALED."
12. **DINAVISA RESOLUTION No. 227** DATED JUNE 20, 2025: "BY WHICH THE CRISIS AND EMERGENCY MANAGEMENT PLAN OF THE NATIONAL HEALTH SURVEILLANCE DIRECTORATE IS APPROVED."
13. **DINAVISA RESOLUTION No. 226** DATED JUNE 20, 2025: "BY WHICH THE PROCEDURES FOR OPENING, RENEWAL OF OPENING AND MODIFICATIONS OF PUBLIC AND PRIVATE ESTABLISHMENTS REGULATED BY DINAVISA ARE REGULATED AND DNVS DG RESOLUTION No. 001/2021 AND DINAVISA RESOLUTION No. 25/2022 ARE REPEALED."
14. **DINAVISA RESOLUTION No. 224** ESTABLISHING THE PROCEDURES FOR POST-REGISTRATION MODIFICATIONS OF BIOLOGICAL MEDICINES, IN ACCORDANCE WITH WORLD HEALTH ORGANIZATION GUIDE No. 1011,2018: GUIDELINES ON PROCEDURES AND DATA REQUIREMENTS FOR CHANGES IN REGISTERED BIOLOGICAL MEDICINES.
15. **DINAVISA RESOLUTION No. 221** ESTABLISHING THE PROCEDURES FOR SAMPLING MEDICINES AND RELATED PRODUCTS, REGULATED BY DINAVISA
16. **DINAVISA RESOLUTION No. 219** APPROVING THE FEE FOR THE ACCREDITATION OF HEALTH RESEARCH ETHICS COMMITTEES (CEIS) BEFORE DINAVISA.
17. **DINAVISA RESOLUTION No. 215/2025** "WHICH ESTABLISHES THE REQUIREMENTS FOR THE RENEWAL OF THE SANITARY REGISTRATION OF BIOLOGICAL MEDICINES AND VACCINES, AND REPEALS ARTICLES 18 AND 19 OF DINAVISA RESOLUTION No. 233/2024"
18. **DINAVISA RESOLUTION No. 210** DATED JUNE 4, 2025; "WHICH IMPLEMENTS THE QUALITY CONTROL INSPECTION PROGRAM FOR MEDICINES MARKETED WITHIN THE SCOPE OF THE NATIONAL HEALTH SURVEILLANCE DIRECTORATE AND REPEALS DINAVISA RESOLUTION No. 212/2023."
19. **DINAVISA RESOLUTION No. 209** DATED JUNE 4, 2025; "BY WHICH ANNEX I OF DINAVISA RESOLUTION No. 290 DATED MAY 29, 2023 IS MODIFIED."
20. **RESOLUCIÓN DINAVISA Nº 208** DE FECHA 04 DE JUNIO 2025; " POR LA CUAL SE DEFINEN LOS LINEAMIENTOS PARA LA UTILIZACIÓN DE INFORMES Y RESULTADOS EMITIDOS POR LABORATORIOS DE CONTROL DE CALIDAD RECONOCIDOS POR OTRAS AUTORIDADES REGULADORAS NACIONALES PARA LA TOMA DE DECISIONES."
21. **RESOLUCIÓN DINAVISA Nº 203** DE FECHA 03 DE JUNIO DE 2025: "POR LA CUAL REGLAMENTA LA AUTORIZACIÓN DE IMPORTACIÓN DE MEDICAMENTOS Y DISPOSITIVOS MÉDICOS QUE NO CUENTEN CON REGISTROS SANITARIOS EMITIDOS POR LA DINAVISA, DESTINADOS AL USO COMPASIVO."
22. **RESOLUCION DINAVISA N°192** POR LA CUAL SE PRORROGA LA VIGENCIA DE LA RESOLUCION DINAVISA N°148-24 POR LA CUAL SE EMITE EL LISTADO ANUAL OFICIAL DE LOS PAISES EN EL CUMPLIMIENTO AL ARTICULO 3° DE LA LEY N° 7256/2024
23. **RESOLUCIÓN DINAVISA N° 189** DE FECHA 28 DE MAYO DE 2025 "POR LA CUAL SE REGLAMENTA LA AUTORIZACIÓN DE USO TEMPORAL DE MEDICAMENTOS, DISPOSITIVOS MÉDICOS Y OTROS PRODUCTOS SUJETOS A REGULACIÓN SANITARIA, QUE NO CUENTEN CON REGISTROS SANITARIOS EMITIDOS POR LA DINAVISA, EN SITUACIONES DE PANDEMIAS, EPIDEMIAS O EMERGENCIAS SANITARIAS, O SITUACIONES DE URGENCIA O CATÁSTROFE, QUE SIGNIFIQUEN GRAVE RIESGO PARA LA SALUD O LA VIDA DE LAS PERSONAS Y SEAN DECLARADAS POR LAS AUTORIDADES COMPETENTES.
24. **RESOLUCIÓN DINAVISA N° 186** DE FECHA 27 DE MAYO DE 2025 " POR LA CUAL SE ESTABLECEN LOS REQUISITOS Y LAS CONDICIONES PARA LA EMISIÓN DE REGISTRO SANITARIO CONDICIONAL DE MEDICAMENTOS DE SÍNTESIS QUÍMICA Y MEDICAMENTOS BIOLÓGICOS, Y SE ABROGA LA RESOLUCIÓN DINAVISA Nº 338/2022."
25. **RESOLUCIÓN DINAVISA N° 185** DE FECHA 27 DE MAYO DE 2025 " POR LA CUAL SE APRUEBAN LOS REQUISITOS DE BUENAS PRÁCTICAS DE OBTENCIÓN, PROCESAMIENTO, ALMACENAMIENTO, DISTRIBUCIÓN Y USO DE PLASMA SANGUÍNEO HUMANO PARA SU LIBERACIÓN COMO MATERIA PRIMA PARA LA ELABORACIÓN DE MEDICAMENTOS HEMODERIVADOS."
26. **RESOLUCIÓN DINAVISA Nº 168** POR LA CUAL SE ESTABLECE EL PROCEDIMIENTO PARA LA RENOVACIÓN DEL REGISTRO SANITARIO DE MEDICAMENTOS DE SINTESIS QUIMICA.

27. **RESOLUCION DINAVISA N°152** POR LA CUAL SE REGLAMENTA LA COMERCIALIZACION DE PRODUCTOS AFINES, EN FARMACIAS HABILITADAS POR LA DINAVISA
28. **RESOLUCION DINAVISA N°151** POR LA CUAL SE ESTABLECE EL PROCEDIMIENTO PARA LAS MODIFICACIONES POST-REGISTRO SANITARIOS DE MEDICAMENTOS DE SISTEMAS QUIMICAS
29. **RESOLUCIÓN DINAVISA N°149** POR LA CUAL SE ESTABLECEN LOS CRITERIOS PARA EL ANÁLISIS DE RIESGO A EFECTOS DE REALIZAR INSPECCIONES DE VIGILANCIA Y CONTROL DE MERCADO APLICADO A PRODUCTOS ILEGÍTIMOS, PAUTAS DE EVALUACIÓN, SE DISPONE SU IMPLEMENTACIÓN Y SE ABROGA LA RESOLUCIÓN DINAVISA N° 187/2024.
30. **RESOLUCION DINAVISA N°148** POR LA CUAL SE ESTABLECE EL PROCEDIMIENTO ABREVIADO PARA LA OBTENCION DEL REGISTRO SANITARIO DE MEDICAMENTOS DE SINTESIS QUIMICA.
31. **DINAVISA RESOLUTION No. 147** ESTABLISHING THE ORDINARY PROCEDURE FOR OBTAINING HEALTH REGISTRATION FOR CHEMICALLY SYNTHESIS MEDICINES.
32. **DINAVISA RESOLUTION No. 139** WHICH ESTABLISHES THE EXTERNAL REFERENCE PRICE (REP) FOR INNOVATIVE PRODUCTS.
33. **DINAVISA RESOLUTION No. 115** WHICH DEFINES THE ACTIVITIES CARRIED OUT IN THE PROCESS OF RELEASE OF VACCINE BATCHES AND BLOOD DERIVATIVES.
34. **DINAVISA RESOLUTION No. 112** APPROVING THE FEES CORRESPONDING TO THE VERIFICATION OF GOOD LABORATORY PRACTICES
35. **DINAVISA RESOLUTION No. 90** WHICH ESTABLISHES FLUOXETINE AS A REFERENCE PRODUCT FOR THE ACTIVE INGREDIENT, FOR DEMONSTRATION PURPOSES
36. **DINAVISA RESOLUTION No. 89** ESTABLISHING THE REQUIREMENTS FOR THE REGISTRATION AND RENEWAL OF PHYTOTHERAPEUTIC MEDICINES
37. **DINAVISA RESOLUTION No. 88** ESTABLISHING THE PROCEDURE FOR ISSUING CERTIFICATE OF IMPLEMENTATION OF GOOD PHARMACOVIGILANCE PRACTICES (GPPV) BY HOLDERS OF HEALTH REGISTRIES FOR MEDICINES
38. **DINAVISA RESOLUTION No. 68_2025** WHICH REGULATES GOOD LABORATORY PRACTICES (GLP) FOR FOOD AND RELATED PRODUCTS, APPROVES THE GLP MANUAL AND ESTABLISHES THE CERTIFICATION PROCEDURE FOR SAME.

Resoluciones Año 2024

Resoluciones Año 2023

Resoluciones Año 2022

DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY | PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

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